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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,547	10/26/2005	Harvey Kaplan	1658-8/AMK	1415
7590 Adrian M Kaplan Dimock Stratton 20 Queen Street West Suite 3202 PO Box 102 Toronto Ontario M5H 3R3, CANADA			EXAMINER YOUNG, HUGH PARKER	
			ART UNIT	PAPER NUMBER
			1654	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		02/15/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/524,547		KAPLAN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Hugh P. Young		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

This is the first office action on application No: 10,524,547. There are twenty-two claims pending, all of which are the subject of this restriction requirement.

#### ***Informalities in the claims***

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 14, 14-22 been renumbered 14, 15-23.

#### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-6, drawn to methods of glycating a protein with a reducing sugar, *in vacuo*.

Group II, claims 7-11, drawn to methods of homogeneously cross-linking a protein with a reducing sugar, *in vacuo*.

Group III, claims 12-23, drawn to methods of heterogeneously cross-linking two proteins with a reducing sugar, *in vacuo*.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, there is no nexus

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between the ten groups regarding the methods of Group I. Groups I-II required different method steps and different components with different end results. There is no general inventive concept over the Groups, especially where the method steps in Groups II-III are for using different steps and different components with differing end results, in the making of final products that are drawn to, variously, adding sugar moieties to proteins, or using sugar moieties to join form either homo- or hetero-polymers. Thus, Groups I-III lack a single general inventive concept and are patentably distinct.

3. Furthermore, MPEP Appendix B Lack of Unity states:

(d) Illustrations of Particular Situations. There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:

- (i) combinations of different categories of claims;
- (ii) so-called "Markush practice"; and
- (iii) intermediate and final products.

Principles for the interpretation of the method contained in Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of Rule 13.2. Examples to assist in understanding the interpretation on the three areas of special concern referred to in the preceding paragraph are set out below.

(e) Combinations of Different Categories of Claims. The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

- (iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process, it being understood that a process is specially adapted for the manufacture of a product if it inherently results in the product and that an apparatus or means is specifically designed for carrying out

a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process. Also an apparatus or means shall be considered to be "specifically designed for carrying out" a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### ***Inventorship***

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Conclusion***

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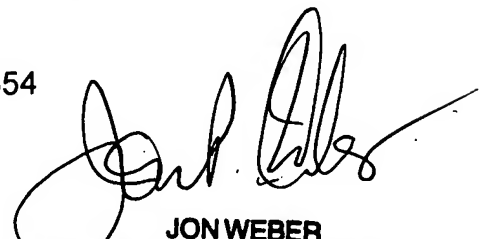
5. No claims are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D.

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**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**